Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Stasis 1 Coagulation Control

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Stasis 1 Coagulation Control (Normal)

Common Name: Normal Coagulation Control

Classification Name: Plasma, Coagulation Control, a class II device as per 21 CFR section 864.5425 (Product Code GGC). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Coagulation Control Level I (K984129)

Description

Wortham Laboratories Stasis 1 Coagulation Control (Normal) is a liquid stable citrated plasma obtained from healthy donors. Stabilizers and buffers have been added to the plasma. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found to be non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Stasis 1 Coagulation Control (Normal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Fibrinogen assays. It will yield PT, APTT, and Fibrinogen values in the normal range.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	Routine coagulation for PT, PTT, fibrinogen assays in the normal range			Routine coagulation for PT, PTT, fibrinogen assays in the normal range		
Control Composition	Liquid Human citrated plasma			Lypholyzed human citrated plasma		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			35 months @ 2-8° C, lypholyzed 8 hours @ 2-8° C, rehydrated		
Reference Values	CV%		PT	CV%		PT
	within-run (ISI=1.54)		0.75%	within-run (ISI=1.54)		0.90%
	within-run (ISI=1.20)		0.88%	within-run (ISI=1.20)		1.40%
	run-run (ISI=1.54)		0.67%	run-run (ISI=1.54)		0.85%
	run-run (ISI=1.20)		0.89%	run-run (ISI=1.20)		1.38%
	CV%		APTT	CV%		APTT
	within-run (Kaolin)		0.63%	within-run (Kaolin)		1.54%
	within-run (Ellagic-Acid)		0.62%	within-run (Ellagic-Acid)		0.85%
	run-run (Kaolin)		0.61%	run-run (Kaolin)		1.20%
	run-run (Ellagic Acid)		0.60%	run-run (Ellagic Acid)		0.85%
	CV%		Fibrinogen	CV%		Fibrinogen
	within-run		0.56%	within-run		0.59%
	run-run		0.57%	run-run		0.60%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	PT	11.67	11.5-11.8 sec	PT	11.66	11.4-11.9 sec
	APTT:	29.51	29.3-29.7 sec	APTT:	28.38	28.0-28.8 sec
	Fibrinogen:	306.3	301-313 g/dl	Fibrinogen:	306.3	297-315 g/dl
Storage	≤ -2° C			2 - 8° C		
Assay Factors	PT, APTT, Fibrinogen			PT, APTT, Fibrinogen		

Conclusions

Stasis 1

Wortham Laboratories Stasis 1 and Pacific Hemostasis Coagulation Control Level I have the same intended use, as normal controls for the quantitative measurement of the Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and fibrinogen levels. Both are preparations of citrated plasma obtained from normal donors with added stabilizers and buffers.

Mechanical assays of Stasis 1 to the predicate normal plasma control with two different sensitive thromboplastin reagents, with an ISI of 1.20 and 1.58, yielded a within-run standard deviation of 0.0809 and 0.0922 for Stasis 1 respectively, compared to a 0.1714 and a 0.1050 SD for the predicate control from the same reagents. A run-run precision of Stasis 1 produced a 0.1026 and 0.0784 SD with the two thromboplastin reagents, compared to 0.1733 and 0.0987 SD of Pacific Hemostasis Control.

Mechanical measurements of the APTT in both Stasis 1 and Pacific Hemostasis Level I Control with two different activator reagents, Kaolin and ellagic acid, produced a within-run 0.0863 and a 0.1792 standard deviation, respectively, while the predicate control yielded a 0.1989 and a 0.2455 SD. A run-run precision of the Stasis 1 Control measured at 0.1705 and 0.1749 SD to the two APTT activators, contrasted to Pacific Hemostasis Level I Controls 0.3339 and 0.2453 SD.

The processing of the Fibrinogen levels in both study graphs on the fibrometer instrument produced a within-run 0.0850 and a 0.0858 run-run standard deviation for Stasis 1, which a within-run 0.089 SD and run-run 0.0900 SD was observed in the Pacific Hemostasis Level 1 Control.

Reproducibility of the two controls yielded a 0.86% within-run coefficient of variation and a run-run 0.89% CV for Stasis 1, compared respectively to the predicate control of 1.36% CV and 1.38% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Stasis 1 Coagulation Control to Pacific Hemostasis Coagulation Control Level I. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Stasis 2 Coagulation Control

The assigned 510K number is: K060968

Applicant:	Wortham Laboratories, Inc. 6340 Bonny Oaks Dr Chattanooga, TN 37416 Tel: (423) 296-0090 Fax: (423) 296-0188
Contact:	Leon Wortham
Date:	April 6, 2007
Device Name:	Wortham Laboratories Stasis 2 Coagulation Control (Abnormal)
Common Name:	Abnormal Coagulation Control
Classification Name:	Plasma, Coagulation Control, a class II device as per 21 CFR section 864.5425 (Product Code GGC). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.
Predicate:	Pacific Hemostasis Coagulation Control Level II (K984130)

Description

Wortham Laboratories Stasis 2 Coagulation Control (Abnormal) is a liquid stable citrated plasma obtained from healthy donors. Stabilizers and buffers have been added to the plasma. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found to be non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Stasis 2 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the moderate abnormal range.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	Routine coagulation for PT, PTT, assays in the moderately abnormal range			Routine coagulation for PT, PTT, assays in the moderately abnormal range		
Control Composition	Liquid Human citrated plasma			Lypholyzed human citrated plasma		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			34 months @ 2-8° C, lypholyzed 8 hours @ 2-8° C, rehydrated		
Reference Values	CV%		PT	CV%		PT
	within-run (ISI=1.54)		1.01%	within-run (ISI=1.54)		1.41%
	within-run (ISI=1.20)		1.10%	within-run (ISI=1.20)		1.28%
	run-run (ISI=1.54)		0.98%	run-run (ISI=1.54)		1.30%
	run-run (ISI=1.20)		1.01%	run-run (ISI=1.20)		1.19%
	CV%		APTT	CV%		APTT
	within-run (Kaolin)		0.76%	within-run (Kaolin)		1.00%
	within-run (Ellagic-Acid)		0.50%	within-run (Ellagic-Acid)		0.91%
	run-run (Kaolin)		0.76%	run-run (Kaolin)		1.06%
	run-run (Ellagic Acid)		0.48%	run-run (Ellagic Acid)		0.90%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	PT	20.14	19.9-20.3 sec	PT	20.25	19.7-20.8 sec
	APTT:	55.75	54.9-56.6 sec	APTT:	55.01	53.9-56.2 sec
Storage	≤ -2° C			2 - 8° C		
Assay Factors	PT, APTT			PT, APTT		

Conclusions

Stasis 2

Wortham Laboratories Stasis 2 and Pacific Hemostasis Coagulation Control Level II have the same intended use, as normal controls for the quantitative measurement of the Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). Both are preparations of citrated plasma obtained from normal donors with added stabilizers and buffers.

Mechanical assays of Stasis 2 to the predicate moderately abnormal plasma control with two different sensitive thromboplastin reagents, 1.20 ISI and 1.58 ISI, yielded a standard deviation of 0.5992 and 0.2023 for Stasis 2 respectively, compared to a 0.4638 SD and a 0.2856 SD for the predicate control from the same reagents. A run-run precision of Stasis 2 produced a 0.3664 and 0.1984 SD with the two thromboplastin reagents, compared to 0.4296 and 0.2644 SD of Pacific Hemostasis Control.

Mechanical measurements of the APTT in both Stasis 2 and Pacific Hemostasis Level II Control with two different activator reagents, Kaolin and ellagic acid, produced a 0.4135 and a 0.2341 standard deviation, respectively, while the predicate control yielded a 0.5721 and a 0.4045 SD. A run-run precision of the Stasis 2 Control measured at 0.4136 and 0.2233 SD to the two APTT activators, contrasted to Pacific Hemostasis Level II Controls 0.5628 and 0.4043 SD.

Reproducibility of the two controls yielded a 1.10% within-run coefficient of variation and a run-run 1.01% CV for Stasis 2, compared respectively to the predicate control of 1.28% CV and 1.19% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Stasis 2 Coagulation Control to Pacific Hemostasis Coagulation Control Level II. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

MAY 15 2007

Wortham Laboratories, Inc.

Premarket Notification 510 (k) Summary

Stasis 3 Coagulation Control

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Stasis 3 Coagulation Control (Abnormal)

Common Name: Abnormal Coagulation Control

Classification Name: Plasma, Coagulation Control, a class II device as per 21 CFR section 864.5425 (Product Code GGC). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Coagulation Control Level III (K984131)

Description

Wortham Laboratories Stasis 3 Coagulation Control (Abnormal) is a liquid stable citrated plasma obtained from healthy donors. Stabilizers and buffers have been added to the plasma. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found to be non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Stasis 3 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the strongly abnormal range.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	Routine coagulation for PT, PTT, assays in the high abnormal range			Routine coagulation for PT, PTT, assays in the high abnormal range		
Control Composition	Liquid Human citrated plasma			Lypholyzed human citrated plasma		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			35 months @ 2-8° C, lypholyzed 8 hours @ 2-8° C, rehydrated		
Reference Values	CV%		PT	CV%		PT
	within-run (ISI=1.54)		1.45%	within-run (ISI=1.54)		1.68%
	within-run (ISI=1.20)		1.36%	within-run (ISI=1.20)		1.52%
	run-run (ISI=1.54)		1.46%	run-run (ISI=1.54)		1.70%
	run-run (ISI=1.20)		1.44%	run-run (ISI=1.20)		1.34%
	CV%		APTT	CV%		APTT
	within-run (Kaolin)		0.80%	within-run (Kaolin)		1.12%
	within-run (Ellagic-Acid)		0.76%	within-run (Ellagic-Acid)		1.12%
	run-run (Kaolin)		0.75%	run-run (Kaolin)		1.15%
	run-run (Ellagic Acid)		0.75%	run-run (Ellagic Acid)		1.11%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	PT	32.50	32.0-33.0 sec	PT	32.49	31.4-33.6 sec
	APTT:	70.49	69.4-71.5 sec	APTT:	70.13	68.8-71.4 sec
Storage	≤ -2° C			2 - 8° C		
Assay Factors	PT, APTT			PT, APTT		

Conclusions

Stasis 3

Wortham Laboratories Stasis 3 and Pacific Hemostasis Coagulation Control Level III have the same intended use, as normal controls for the quantitative measurement of the Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). Both are preparations of citrated plasma obtained from normal donors with added stabilizers and buffers.

Mechanical assays of Stasis 3 to the predicate moderately abnormal plasma control with two different sensitive thromboplastin reagents, 1.20 ISI and 1.58 ISI, yielded a standard deviation of 0.8385 and 0.4721 for Stasis 3 respectively, compared to a 0.9333 and a 0.5467 for the predicate control from the same reagents. A run-run precision of Stasis 3 produced a 0.841 and 0.4712 SD with the two thromboplastin reagents, compared to 0.9696 and 0.5512 SD of Pacific Hemostasis Control.

Mechanical measurements of the APTT in both Stasis 3 and Pacific Hemostasis Level III Control with two different activator reagents, Kaolin and ellagic acid, produced a 0.5278 and a 0.4928 standard deviation, respectively, while the predicate control yielded a 0.6465 and a 0.7160 SD. A run-run precision of the Stasis 3 Control measured at 0.5273 and 0.4860 SD to the two APTT activators, contrasted to Pacific Hemostasis Level III Controls.0.8029 and 0.7133 SD.

Reproducibility of the two controls yielded a 1.35% within-run coefficient of variation and a run-run 1.36% CV for Stasis 3, compared respectively to the predicate control of 1.52% CV and 1.58% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Stasis 3 Coagulation Control to Pacific Hemostasis Coagulation Control Level III. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

Premarket Notification 510 (k) Summary

MAY 15 2007

Serathan-B PT Reagent

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Serathan-B PT Reagent.

Common Name: Prothrombin Time

Classification Name: Prothrombin Time Test, is a class II device, as per 21 CFR 864.7750 (Product Code GJS). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Thromboplastin-D (K994100)

Description

Wortham Laboratories Serathan-B PT Reagent is a liquid stable extract of rabbit thromboplastin containing calcium, stabilizer and buffer. Serathan-B is an in-vitro diagnostic reagent intended for use for the performance of Prothrombin Time (PT) testing and quantitative PT-based factor assays for Factors II, V. VII and X.

Intended Use

Wortham Laboratories Serathan-B PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-B is a moderately sensitive thromboplastin reagent.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device				Predicate			
Intended Use	Performance of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway				Performance of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway			
Reagent Composition	Liquid Rabbit Thromboplastin				Lypholyzed Rabbit Thromboplastin			
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C				30 months @ 2-8° C, lypholyzed 7 days @ 2-8° C, rehydrated			
Reference Values	within-run			CV%	within-run			CV%
	Level 1			0.80%	Level 1			0.90%
	Level 2			1.27%	Level 2			1.41%
	Level 3			1.42%	Level 3			1.68%
	run-run			CV%	run-run			CV%
	Level 1			1.75%	Level 1			0.85%
	Level 2			1.22%	Level 2			1.30%
	Level 3			1.44%	Level 3			1.70%
	Lupus Sensitivity			CV%	Lupus Sensitivity			CV%
				0.32%				1.67%
	Factor Assay			CV%	Factor Assay			CV%
	Factor II			0.00%	Factor II			0.39%
	Factor V			0.26%	Factor V			0.32%
	Factor VII			0.19%	Factor VII			0.32%
	Factor X			0.19%	Factor X			0.31%
Expected Range	Mean (sec)				Mean (sec)			
%	II	V	VII	X	II	V	VII	X
100	11.00	11.49	11.40	11.60	10.88	11.38	11.28	11.48
50	11.01	11.89	12.41	11.39	10.88	11.80	12.32	13.13
40	11.49	12.41	13.09	13.82	11.41	12.29	12.92	13.56
30	11.79	13.19	13.90	14.91	11.70	13.00	13.71	14.73
20	12.30	14.70	14.79	16.32	12.22	14.50	14.50	16.08
10	13.71	17.12	16.48	20.02	13.63	16.93	16.17	19.81
Linearity	11.6 36.2 sec				11.1 – 35.6 sec			
Storage	≤ -2° C				2 - 8° C			
Assay Factors	PT, Fibrinogen, Factors				PT, Fibrinogen, Factors			
	II, V, VII, X				II, V, VII, X			

Conclusions

Serathan-B

Wortham Laboratories Serathan-B and Pacific Hemostasis Thromboplastin-D reagents have the same intended use, as for the quantitative measurement of the Prothrombin Time (PT), and Factors II, V, VII, X. Both reagents are preparations of rabbit thromboplastin and calcium chloride, with an International Sensitivity Index of 1.5 – 1.7.

All assays were measured on the fibrometer yielding a PT standard deviation of 0.0869, 0.2033 and 0.4721 for Serathan-B on Level 1, Level 2, Level 3 plasma controls, respectively, compared to Pacific Hemostasis Thromboplastin-D of 0.1050, 0.2856, 0.5467 standard deviation on the same controls.

Comparing the precision of the two reagents in the factor assays produced a standard deviation of 0.03, 0.03, 0.022 and 0.022 for Factors II, V, VII, X, respectively for Serathan-B, contrasted to 0.043, 0.036, 0.036, and 0.036 for Thromboplastin-D.

Reproducibility of the two reagents yielded a 0.80% within-run coefficient of variation and a run-run 0.75% CV for Serathan-B, compared respectively to the predicate control of 0.91% CV and 0.89% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Serathan-B to Pacific Hemostasis Thromboplastin-D. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

Wortham Laboratories, Inc.

K060968

Premarket Notification 510 (k) Summary

Serathan-A PT Reagent

MAY 15 2007

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Serathan-A PT Reagent.

Common Name: Prothrombin Time

Classification Name: Prothrombin Time Test, is a class II device, as per 21 CFR 864.7750 (Product Code GJS). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Thromboplastin-DS (K940082)

Description

Wortham Laboratories Serathan-A PT Reagent is a liquid stable extract of rabbit thromboplastin containing calcium, stabilizer and buffer. Serathan-A is an in-vitro diagnostic reagent intended for use for the performance of Prothrombin Time (PT) testing and quantitative PT-based factor assays for Factors II, V. VII and X.

Intended Use

Wortham Laboratories Serathan-A PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-A is a highly sensitive thromboplastin reagent.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device				Predicate			
Intended Use	Performance of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway				Performance of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway			
Reagent Composition	Liquid Rabbit Thromboplastin				Lypholyzed Rabbit Thromboplastin			
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C				30 months @ 2-8° C, lypholyzed 7 days @ 2-8° C, rehydrated			
Reference Values	within-run		CV%		within-run		CV%	
	Level 1		0.89%		Level 1		1.36%	
	Level 2		1.09%		Level 2		1.28%	
	Level 3		1.25%		Level 3		1.52%	
	run-run		CV%		run-run		CV%	
	Level 1		0.88%		Level 1		1.38%	
	Level 2		1.08%		Level 2		1.19%	
	Level 3		1.28%		Level 3		1.58%	
	Lupus Sensitivity		CV%		Lupus Sensitivity		CV%	
			0.29%				2.04%	
	Factor Assay		CV%		Factor Assay		CV%	
	Factor II		1.25%		Factor II		0.42%	
	Factor V		0.25%		Factor V		0.37%	
	Factor VII		0.25%		Factor VII		0.38%	
	Factor X		0.18%		Factor X		0.32%	
Expected Range	Mean (sec)				Mean (sec)			
%	II	V	VII	X	II	V	VII	X
100	11.79	11.79	11.99	11.90	11.69	11.67	11.90	11.80
50	11.80	13.41	12.79	13.11	11.72	13.31	12.70	12.98
40	12.02	14.20	12.98	13.60	11.92	14.09	12.92	13.51
30	12.38	15.20	13.82	14.52	12.30	15.13	13.72	14.38
20	12.99	16.29	14.11	15.21	12.80	16.22	14.02	15.10
10	14.31	18.66	15.51	17.52	14.02	18.48	15.38	17.30
Linearity	12.1 – 41.9 sec				11.9 – 41.1 sec			
Storage	≤ -2° C				2 - 8° C			
Assay Factors	PT, Fibrinogen, Factors				PT, Fibrinogen, Factors			
	II, V, VII, X				II, V, VII, X			

Conclusions

Serathan-A

Wortham Laboratories Serathan-A and Pacific Hemostasis Thromboplastin-DS reagents have the same intended use, as for the quantitative measurement of the Prothrombin Time (PT), and Factors II, V, VII, X. Both reagents are preparations of rabbit thromboplastin and calcium chloride, with an International Sensitivity Index of 1.0 – 1.2.

All assays were measured on the fibrometer yielding a PT standard deviation of 0.1135, 0.3977 and 0.7746 for Serathan-A on Level 1, Level 2, Level 3 plasma controls, respectively, compared to Pacific Hemostasis Thromboplastin-DS of 0.1694, 0.4320, 0.8556 standard deviation on the same controls.

Comparing the precision of the two reagents in the factor assays produced a standard deviation of 0.030, 0.030, 0.030 and 0.022 for Factors II, V, VII, X, respectively for Serathan-A, contrasted to 0.0497, 0.043, 0.045, and 0.038 for Thromboplastin-DS.

Reproducibility of the two reagents yielded a 1.09% within-run coefficient of variation and a run-run 0.97% CV for Serathan-A, compared respectively to the predicate control of 1.18% CV and 1.21% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Serathan-A to Pacific Hemostasis Thromboplastin-DS. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Intrin-EA APTT Reagent

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Intrin-EA APTT Reagent.

Common Name: Activated Partial Thromboplastin Time (APTT)

Classification Name: Activated Partial Thromboplastin is a class II device, as per 21 CFR 864.7925 (Product Code GFO). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis APTT-LS (K891337)

Description

Wortham Laboratories Intrin-EA APTT reagent is intended for use in determining activated partial thromboplastin time (APTT) and coagulation factor assays that are based on a modified APTT. The capacity of blood to form a fibrin clot by way of the intrinsic hemostatic pathway requires coagulation factors XII, XI, IX, VIII, platelet lipids and calcium. The assay is performed by the addition of a suspension of rabbit cephalin with the surface activator ellagic acid.

Intended Use

Wortham Laboratories Intrin-EA APTT is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-EA reagent is sensitive to mild coagulopathies.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device	Predicate
Intended Use	Performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway	Performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway
Reagent Composition	Liquid Rabbit Thromboplastin with ellagic acid activator	Liquid Rabbit Thromboplastin with ellagic acid activator
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C	22 months @ 2-8° C, lypholyzed 30 days @ 2-8° C, rehydrated

Reference Values	within-run	CV%	within-run	CV%
	Level 1	0.51%	Level 1	0.85%
	Level 2	0.41%	Level 2	0.91%
	Level 3	0.73%	Level 3	1.12%
	run-run	CV%	run-run	CV%
	Level 1	0.51%	Level 1	0.85%
	Level 2	0.44%	Level 2	0.90%
	Level 3	0.71%	Level 3	1.11%
	Heparin Sensitivity	CV%	Heparin Sensitivity	CV%
	0.25 U/ml	0.71%	0.25 U/ml	1.03%
	0.35 U/ml	0.54%	0.35 U/ml	0.91%
	Lupus Sensitivity	CV%	Lupus Sensitivity	CV%
		4.39%		7.81%
	Factor Assay	CV%	Factor Assay	CV%
	Factor VIII	0.17%	Factor VIII	0.23%
	Factor IX	0.17%	Factor IX	0.24%
	Factor XI	0.14%	Factor XI	0.29%
	Factor XII	0.13%	Factor XII	0.26%

Expected Range	Mean (sec)				Mean (sec)			
%	VIII	IX	XI	XII	VIII	IX	XI	XII
100	29.36	28.54	29.47	26.82	28.23	27.48	28.32	25.78
50	33.86	32.38	34.74	29.89	32.57	31.26	33.36	28.65
40	35.08	34.03	36.26	31.14	33.83	33.02	35.03	29.78
30	37.33	36.34	38.61	32.23	36.13	35.12	37.30	31.09
20	40.47	38.64	41.35	33.33	39.20	37.40	40.14	32.07
10	45.10	40.89	46.84	35.04	43.78	39.86	45.70	33.21

Linearity	29.0 – 70.7 sec	28.5 – 69.6 sec
Storage	≤ -2° C	2 - 8° C
Assay Factors	APTT, Heparin, Factors VIII, IX, XI, XII	APTT, Heparin, Factors VIII, IX, XI, XII

Conclusions

Intrin-EA

Wortham Laboratories Intrin-EA and Pacific Hemostasis APTT-LS reagents have the same intended use, as for the quantitative measurement of the Activated Partial Thromboplastin Time (APTT), Heparin, and Factors VIII, IX, XI, XII. Both reagents are preparations of rabbit thromboplastin and ellagic acid as an activator.

All assays were measured on the fibrometer yielding an APTT standard deviation of 0.1483, 0.1968 and 0.4961 for Intrin-EA on Level 1, Level 2, Level 3 plasma controls, respectively, compared to Pacific Hemostasis APTT-LS of 0.1908, 0.4030, 0.8900 standard deviation on the same controls.

Intrin-EA sensitivity to heparin at 0.25 U/ml and 0.35 U/ml, yielded a 0.2236 standard deviation to both levels of heparin compared to 0.3078 and 0.3664 standard deviation, respectively, in the predicate product.

Comparing the precision of the two reagents in the factor assays produced a standard deviation of 0.049, 0.048, 0.043, and 0.036 SD for Factors VIII, IX, XI, XII, respectively for Intrin-EA, to 0.064, 0.065, 0.083, and 0.068 SD for APTT-LS.

Reproducibility of the two reagents yielded a 0.71% coefficient of variation at 0.25 U/ml and 0.54% CV at 0.35 U/ml heparin, compared to APTT-LS 1.03% CV and 0.91% CV, respectively.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Intrin-EA to Pacific Hemostasis APTT-LS. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Intrin-SI APTT Reagent

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Intrin-SI APTT Reagent is a liquid stable extract of rabbit brain thromboplastin, containing stabilizers and buffers. Intrin-SI is an in-vitro diagnostic reagent intended for use for the performance of a citrated Partial Thromboplastin Time (APTT) testing and quantitative PTT-based factor assays for Factors XII, XI, IX and VIII.

Common Name: Activated Partial Thromboplastin Time (APTT)

Classification Name: Activated Partial Thromboplastin is a class II device, as per 21 CFR 864.7925 (Product Code GFO). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Kontact (K023362)

Description

Wortham Laboratories Intrin-SI APTT reagent is intended for use in determining activated partial thromboplastin time (APTT) and coagulation factor assays that are based on a modified APTT. The capacity of blood to form a fibrin clot by way of the intrinsic hemostatic pathway requires coagulation factors XII, XI, IX, VIII, platelet lipids and calcium. The assay is performed by the addition of a suspension of rabbit cephalin with the surface activator Kaolin.

Intended Use

Wortham Laboratories Intrin-SI is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-SI reagent is sensitive to heparin and lupus anticoagulant plasmas.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device				Predicate			
Intended Use	Performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway				Performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway			
Reagent Composition	Liquid Rabbit Thromboplastin with a silicon activator				Liquid Rabbit Thromboplastin with a silicon activator			
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C				12 months @ 2-8° C 30 days @ 2-8° C, open			
Reference Values	within-run			CV%	within-run			CV%
	Level 1			0.29%	Level 1			1.54%
	Level 2			0.74%	Level 2			1.00%
	Level 3			0.75%	Level 3			1.16%
	run-run			CV%	run-run			CV%
	Level 1			0.29%	Level 1			1.20%
	Level 2			0.75%	Level 2			1.01%
	Level 3			0.75%	Level 3			1.15%
	Heparin Sensitivity			CV%	Heparin Sensitivity			CV%
	0.25 U/ml			1.57%	0.25 U/ml			2.30%
	0.35 U/ml			1.53%	0.35 U/ml			2.02%
	Lupus Sensitivity			CV%	Lupus Sensitivity			CV%
				6.37%				16.80%
	Factor Assay			CV%	Factor Assay			CV%
	Factor VIII			0.13%	Factor VIII			0.31%
	Factor IX			0.10%	Factor IX			0.32%
	Factor XI			0.16%	Factor XI			0.26%
	Factor XII			0.18%	Factor XII			0.34%
Expected Range	Mean (sec)				Mean (sec)			
%	VIII	IX	XI	XII	VIII	IX	XI	XII
100	28.52	29.59	29.17	28.56	27.85	28.12	28.05	27.78
50	34.77	34.77	32.78	30.35	33.75	34.08	31.38	29.26
40	38.02	38.02	35.80	34.23	36.14	37.21	34.80	33.13
30	42.31	42.61	39.57	37.83	40.90	41.74	38.52	36.64
20	49.91	50.22	46.00	41.59	47.22	49.16	45.15	40.31
10	57.21	56.14	53.68	48.83	54.18	55.12	52.32	47.67
Storage	≤ -2° C				2 - 8° C			
Assay Factors	APTT, Heparin, Factors				APTT, Heparin, Factors			
	VIII, IX, XI, XII				VIII, IX, XI, XII			

Conclusions

Intrin-SI

Wortham Laboratories Intrin-SI and Pacific Hemostasis Kontact reagents have the same intended use, as for the quantitative measurement of the Activated Partial Thromboplastin Time (APTT), Heparin, and Factors VIII, IX, XI, XII. Both reagents are preparations of rabbit thromboplastin and a silicon activator from kaolin.

All assays were measured on the fibrometer yielding an APTT standard deviation of 0.0863, 0.4135 and 0.5278 for Intrin-SI on Level 1, Level 2, Level 3 plasma controls, respectively, compared to Pacific Hemostasis Kontact of 0.1989, 0.5721, 0.6465 standard deviation on the same controls.

Intrin-SI sensitivity to heparin at 0.25 U/ml and 0.35 U/ml, yielded a 0.2236 standard deviation to both levels of heparin compared to 0.3078 and 0.3664 standard deviation, respectively, in the predicate product.

Comparing the precision of the two reagents in the factor assays produced a standard deviation of 0.036, 0.030, 0.046, and 0.050 SD for Factors VIII, IX, XI, XII, respectively for Intrin-SI, to 0.087, 0.089, 0.074, and 0.096 SD for Kontact.

Reproducibility of the two reagents yielded a 0.67% coefficient of variation at 0.25 U/ml and 0.48% CV at 0.35 U/ml heparin, compared to Kontact 0.94% CV and 0.72% CV, respectively.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Intrin-SI to Pacific Hemostasis Kontact. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

MAY 15 2007

K060968

Wortham Laboratories, Inc.

Premarket Notification 510 (k) Summary

Fibrinogen Control Plasma

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Fibrinogen Control Plasma (Low).

Common Name: Fibrinogen Control Plasma

Classification Name: Plasma, Coagulation Control, is a class II device as per 21 CFR 864.5425 (Product Code GHH). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Fibrinogen Assay (K800826)

Description

Wortham Laboratories Fibrinogen Low Control is a liquid stable preparation of citrated plasma obtained from healthy donors, which contains stabilizers and buffers. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Fibrinogen Control Low, a quantitative control plasma, is intended for use in the quality control of fibrinogen assays.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing			To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing		
Control Composition	Liquid Human citrated plasma			Lypholyzed Human citrated plasma		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			24 months @ 2-8° C, lypholyzed 16 hours @ 2-8° C, rehydrated		
Reference Values	within-run		CV%	within-run		CV%
	Normal		0.56%	Normal		0.59%
	Low		0.60%	Low		0.63%
	run-run		CV%	run-run		CV%
	Normal		0.57%	Normal		0.60%
	Low		0.58%	Low		0.67%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	Normal	306.3	301-313 g/dl	Normal	306.3	297-315 g/dl
	Low	99.1	97-103 g/dl	Low	99.8	97-104 g/dl
Storage	≤ -2° C			2 - 8° C		
Assay Factors	Fibrinogen			Fibrinogen		

Conclusions

Wortham Laboratories Low Fibrinogen Control and Pacific Hemostasis Low Fibrinogen Control have the same intended use, as for the quantitative measurement of fibrinogen levels in human plasma. Both are preparations of citrated human plasma, obtained from normal donors with added stabilizers and buffers.

Mechanical assays produced a standard deviation of 0.092 for Wortham Laboratories Fibrinogen Control, compared to a 0.095 standard deviation for Pacific Hemostasis Fibrinogen Control.

Reproducibility of the two controls yielded a 0.60% within-run coefficient of variation and a run-run 0.58% CV for Wortham Laboratories Fibrinogen Control compared respectively to the predicate control of 0.63% CV and 0.67% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Low Fibrinogen Control to Pacific Hemostasis Low Fibrinogen Control. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Fibrinogen Control Plasma

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Fibrinogen Control Plasma (Normal)

Common Name: Fibrinogen Control Plasma

Classification Name: Plasma, Coagulation Control, is a class II device as per 21 CFR 864.5425 (Product Code GHH). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Fibrinogen Assay (K800826)

Description

Wortham Laboratories Fibrinogen Normal Control is a liquid stable preparation of citrated plasma obtained from healthy donors, which contains stabilizers and buffers. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Fibrinogen Control Normal, a quantitative control plasma, is intended for use in the quality control of fibrinogen assays.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing			To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing		
Control Composition	Liquid Human citrated plasma			Lypholyzed Human citrated plasma		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			24 months @ 2-8° C, lypholyzed 16 hours @ 2-8° C, rehydrated		
Reference Values	within-run		CV%	within-run		CV%
	Normal		0.56%	Normal		0.59%
	Low		0.60%	Low		0.63%
	run-run		CV%	run-run		CV%
	Normal		0.57%	Normal		0.60%
	Low		0.58%	Low		0.67%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	Normal	306.3	301-313 g/dl	Normal	306.3	297-315 g/dl
	Low	99.1	97-103 g/dl	Low	99.8	97-104 g/dl
Storage	≤ -2° C			2 - 8° C		
Assay Factors	Fibrinogen			Fibrinogen		

Conclusions

Wortham Laboratories Normal Fibrinogen Control and Pacific Hemostasis Normal Fibrinogen Control have the same intended use, as for the quantitative measurement of fibrinogen levels in human plasma. Both are preparations of citrated human plasma, obtained from normal donors with added stabilizers and buffers.

Mechanical assays produced a standard deviation of 0.085 for Wortham Laboratories Fibrinogen Control, compared to a 0.089 standard deviation for Pacific Hemostasis Fibrinogen Control.

Reproducibility of the two controls yielded a 0.56% within-run coefficient of variation and a run-run 0.53% CV for Wortham Laboratories Fibrinogen Control compared respectively to the predicate control of 0.59% CV and 0.60% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Normal Fibrinogen Control to Pacific Hemostasis Normal Fibrinogen Control. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Thrombin Reagent

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Thrombin Reagent

Common Name: Thrombin Time Test

Classification Name: Fibrinogen Determination System, class II, 21 CFR 864.7340 (Product Code GJA and KQJ). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Thrombin Reagent (K970645)

Description

Wortham Laboratories Thrombin Reagent is a liquid stable preparation of activated bovine prothrombin proteins (Factor IIa).

Intended Use

Wortham Laboratories Thrombin Reagent is intended for thrombin to convert fibrinogen in the quantitative determination of fibrinogen in plasma samples.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	To determine quantitative level of fibrinogen in plasma sample.			To determine quantitative level of fibrinogen in plasma sample.		
Reagent Composition	Liquid bovine thrombin			Lypholyzed bovine thrombin		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			28 months @ 2-8° C, lypholyzed 1 day @ 2-8° C, rehydrated		
Reference Values			CV%			CV%
	within-run		0.67%	within-run		0.68%
	run-run		0.68%	run-run		0.71%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
		119	118-120 IU/ml		119	118-120 IU/ml
Storage	≤ -2° C			2 - 8° C		
Assay Factors	Fibrinogen			Fibrinogen		

Conclusion

Wortham Laboratories Thrombin Reagent and Pacific Hemostasis Thrombin Reagent have the same intended use, as normal reagents for reactive coagulation assays. Both are preparations of activated bovine prothrombin protein (Factor IIa). The performance data presented here, as well as the indistinguishable intended use and technological characteristics, support the substantial equivalence claim for Wortham Laboratories Thrombin Reagent to Pacific Hemostasis Thrombin Reagent. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Heparin Control Plasma

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Heparin Control Plasma Level 1 (0.25 U/ml)

Common Name: Heparin Control Plasma Level

Classification Name: Plasma, Coagulation Control, is a class II device as per 21 CFR 864.5425 (Product Code GGN). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Heparin Control Level I (K992278)

Description

Wortham Laboratories Heparin Control Level 1 is a liquid stable preparation of citrated plasma obtained from healthy donors, which contains sodium heparin, stabilizers and buffers. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Heparin Control Level 1, is intended as a quality control of the Activated Partial Thromboplastin Time (APTT) during heparin monitoring.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	Used in heparin assay for quality control in monitoring heparin therapy with APTT testing, yielding slightly abnormal range for Level 1 (0.25 U/ml) and marked abnormal range for Level 2 (0.35 U/ml)			Used in heparin assay for quality control in monitoring heparin therapy with APTT testing, yielding slightly abnormal range for Level 1 (0.25 U/ml) and marked abnormal range for Level 2 (0.35 U/ml)		
Control Composition	Liquid Human citrated plasma with heparin			Lypholyzed Human citrated plasma with heparin		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			36 months @ 2-8° C, lypholyzed 8 hours @ 2-8° C, rehydrated		
Reference Values	within-run		CV%	within-run		CV%
	0.25 U/ml		1.82%	0.25 U/ml		2.14%
	0.35 U/ml		1.77%	0.35 U/ml		2.04%
	run-run		CV%	run-run		CV%
	0.25 U/ml		1.92%	0.25 U/ml		2.27%
	0.35 U/ml		1.81%	0.35 U/ml		2.07%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	Level 1	46.82	45.2-48.5 sec	Level 1	46.94	44.8-49.1 sec
	Level 2	63.49	62.4-64.6 sec	Level 2	62.64	60.1-65.2 sec
Storage	≤ -2° C			2 - 8° C		
Assay Factors	Heparin			Heparin		

Conclusions

Wortham Laboratories Heparin Control Level 1 and Pacific Hemostasis Heparin Control Level 1 have the same intended use, as for quality control in monitoring heparin therapy with APTT testing. Both are prepared from porcine heparin in normal human citrated plasma. The APTT value will be in the slightly abnormal range for Level 1 Heparin Control.

Mechanical assays produced a within-run standard deviation of 0.8296 and a 0.8930 run-run standard deviation for Wortham Laboratories Level 1 Heparin Control, compared to the predicate control of 1.0640 and 1.0859 standard deviation, respectively.

Reproducibility of the two controls yielded a 1.33% within-run coefficient of variation and a run-run 1.92% CV for Wortham Laboratories Heparin Control Level 1, compared respectively to the predicate control of 2.15% CV and 2.27% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Heparin Control Level 1 to Pacific Hemostasis Heparin Control Level 1. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

Wortham Laboratories, Inc.

MAY 15 2007

Premarket Notification 510 (k) Summary

Heparin Control Plasma

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Heparin Control Plasma Level 2 (0.35 U/ml).

Common Name: Heparin Control Plasma Level 2

Classification Name: Plasma, Coagulation Control, is a class II device as per 21 CFR 864.5425 (Product Code GGN). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Heparin Control Level II (K992279)

Description

Wortham Laboratories Heparin Control Level 2 is a liquid stable preparation of citrated plasma obtained from healthy donors, which contains sodium heparin, stabilizers and buffers. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Heparin Control Level 2, is intended as a quality control of the Activated Partial Thromboplastin Time (APTT) during heparin monitoring.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	Used in heparin assay for quality control in monitoring heparin therapy with APTT testing, yielding slightly abnormal range for Level 1 (0.25 U/ml) and marked abnormal range for Level 2 (0.35 U/ml)			Used in heparin assay for quality control in monitoring heparin therapy with APTT testing, yielding slightly abnormal range for Level 1 (0.25 U/ml) and marked abnormal range for Level 2 (0.35 U/ml)		
Control Composition	Liquid Human citrated plasma with heparin			Lypholyzed Human citrated plasma with heparin		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			36 months @ 2-8° C, lypholyzed 8 hours @ 2-8° C, rehydrated		
Reference Values	within-run		CV%	within-run		CV%
	0.25 U/ml		1.82%	0.25 U/ml		2.14%
	0.35 U/ml		1.77%	0.35 U/ml		2.04%
	run-run		CV%	run-run		CV%
	0.25 U/ml		1.92%	0.25 U/ml		2.27%
	0.35 U/ml		1.81%	0.35 U/ml		2.07%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	Level 1	46.82	45.2-48.5 sec	Level 1	46.94	44.8-49.1 sec
	Level 2	63.49	62.4-64.6 sec	Level 2	62.64	60.1-65.2 sec
Storage	≤ -2° C			2 - 8° C		
Assay Factors	Heparin			Heparin		

Conclusions

Wortham Laboratories Heparin Control Level 2 and Pacific Hemostasis Heparin Control Level 2 have the same intended use, as for quality control in monitoring heparin therapy with APTT testing. Both are prepared from porcine heparin in normal human citrated plasma. The APTT value will be in the slightly abnormal range for Level 2 Heparin Control.

Mechanical assays produced a within-run standard deviation of 1.1205 and a 1.1496 run-run standard deviation for Wortham Laboratories Level 2 Heparin Control, compared to the predicate control of 1.2775 and 1.2975 standard deviation, respectively.

Reproducibility of the two controls yielded a 1.77% within-run coefficient of variation and a run-run 1.81% CV for Wortham Laboratories Heparin Control Level 2, compared respectively to the predicate control of 2.047% CV and 2.07% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Heparin Control Level 2 to Pacific Hemostasis

Heparin Control Level 2. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

WORTHAM LABORATORIES, INC.

MAY 15 2007

DRAFT
Calcium Chloride
0.02 M

Intended Use

Wortham Laboratories Calcium Chloride Solution 0.02 M ($CaCl_2$) is intended for quantitative use with ellagic acid (Intrin-EA) or silicon particulate activators (Intrin-SI) in performing the activated partial thromboplastin time (APTT) on citrated plasma.

Refer to Catalogue Number 4002-03-1 (Intrin-SI)
Refer to Catalogue Number 4002-03-2 (Intrin-EA)

Reagents

IVD For in vitro diagnostic use

Composition: 0.222% M calcium chloride, 0.1% sodium azide.

Warning: Calcium Chloride Solution contains sodium azide. Sodium azide under acid conditions yields hydrozoic acid, an extremely toxic compound. Dilute with running water before discarding, and then flush with a large volume of water. These precautions are recommended to avoid deposits in metal pipetting in which explosive conditions may develop.

Store this product at ≤ - 2° C.

Materials Provided:
Calcium Chloride (0.02M), 1 x 10 ml

Ordering Information

Cat. No.	Description	Contents
4002-04-1	$CaCl_2$ (0.02M)	10 ml
4002-03-1	Intrin-SI	10 ml
4002-03-2	Intrin-EA	10 ml

WORTHAM LABORATORIES, INC.
CHATTANOOGA, TN 37416 USA

DOC:2019 02/07
Catalogue No. 4002-04-1
CE

K060968

MAY 15 2007

Wortham Laboratories, Inc.

Premarket Notification 510 (k) Summary

Fibrinogen Assay Set

The assigned 510K number is: K060968

Applicant: Wortham Laboratories, Inc.
6340 Bonny Oaks Dr
Chattanooga, TN 37416
Tel: (423) 296-0090
Fax: (423) 296-0188

Contact: Leon Wortham

Date: April 6, 2007

Device Name: Wortham Laboratories Fibrinogen Assay Set

Common Name: Fibrinogen Control Plasma

Classification Name: Plasma, Coagulation Control, is a class II device as per 21 CFR 864.5425 (Product Code GHH). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Predicate: Pacific Hemostasis Fibrinogen Assay (K800826)

Description

Wortham Laboratories Fibrinogen Assay Set contains a liquid stable preparation of citrated plasma obtained from healthy donors, which contains stabilizers, buffers, and a bovine reagent and buffer solution which are also provided in the set. Each unit of source material used in the preparation of the control has been tested by an FDA approved method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV.

Intended Use

Wortham Laboratories Fibrinogen Assay Set, containing a complete set of Normal Fibrinogen Control (200-400 mg/dl), Thrombin Reagent (100 IU/ml), and Fibrinogen Buffer, is intended for use in the quantitative determination of fibrinogen in plasma samples.

Labeling

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence

Characteristics	New Device			Predicate		
Intended Use	To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing			To determine quantitative level of fibrinogen in plasma sample, and for quality control in monitoring heparin therapy with APTT testing		
Reagent Composition	Liquid Bovine Thrombin			Lypholyzed Bovine Thrombin		
Stability	12 months @ ≤ -2° C 30 days @ 2-4° C			24 months @ 2-8° C, lypholyzed 16 hours @ 2-8° C, rehydrated		
Reference Values	within-run		CV%	within-run		CV%
	Normal		0.56%	Normal		0.59%
	Low		0.60%	Low		0.63%
	run-run		CV%	run-run		CV%
	Normal		0.57%	Normal		0.60%
	Low		0.58%	Low		0.67%
Expected Range	Mechanical	Mean	± 2SD	Mechanical	Mean	± 2SD
	Normal	306.3	301-313 g/dl	Normal	306.3	297-315 g/dl
	Low	99.1	97-103 g/dl	Low	99.8	97-104 g/dl
Storage	≤ - 2° C			2 - 8° C		
Assay Factors	Fibrinogen			Fibrinogen		

Conclusions

Wortham Laboratories Fibrinogen Assay Set and Pacific Hemostasis Fibrinogen Assay Set have the same intended use, as for the quantitative measurement of fibrinogen levels in human plasma. Both are preparations of citrated human plasma, obtained from normal donors with added stabilizers and buffers, and using bovine thrombin as the activating reagent.

Mechanical assays produced a standard deviation of 0.085 for Wortham Laboratories Fibrinogen Control, compared to a 0.089 standard deviation for Pacific Hemostasis Fibrinogen Control.

Reproducibility of the two controls yielded a 0.56% within-run coefficient of variation and a run-run 0.53% CV for Wortham Laboratories Fibrinogen Control compared respectively to the predicate control of 0.59% CV and 0.60% CV.

The performance data presented here, as well as the undistinguishable intended use and technological characteristics support the substantial equivalence claim for Wortham Laboratories Fibrinogen Assay Set to Pacific Hemostasis Fibrinogen Assay Set. Based on the data provided, it is our conclusion that these two products are substantially equivalent.

K060968

WORTHAM LABORATORIES, INC.

MAY 15 2007

DRAFT

Fibrinogen Buffer

Intended Use

Buffer is designed as a diluent for fibrinogen studies.

Reagents

IVD For in vitro diagnostic use

Fibrinogen Buffer : 1.3% TAPSO Buffer, 0.9% sodium chloride, 0.1% sodium azide and stabilizers; pH 7.35 ± 0.05.

Store at ≤ - 2° C. Unused portions of open bottles will remain stable when stored at 2-4°C unless contaminated.

Avoid contamination by exercising care during multiple pipettings. Physical signs of deterioration are limited to visual microbial contamination.

Warning: Fibrinogen Buffer contains sodium azide. Sodium azide under acidic conditions yields hydrozoic acid, and extremely toxic compound. Azide compounds should be flushed with large volumes of water. Those precautions are recommended to avoid deposits in metal pipes in which explosive conditions may develop.

Ordering Information

Cat No.	Description	Contents
4002-05-3	Fibrinogen Buffer	100 ml
4002-05-1	Fibrinogen Control, Normal	10 ml
4002-05-2	Fibrinogen Control, Low	10 ml
4002-05-3	Fibrinogen Assay Set	
	Fibrinogen Control Normal	5 ml
	Thrombin Reagent	5 ml
	Fibrinogen Buffer	200 ml

WORTHAM LABORATORIES, INC.
CHATTANOOGA, TN 37416 USA

DOC:2026 02/07
Catalogue No. 4002-05-3
CE

DEPARTMENT OF HEALTH & HUMAN SERVICES.

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 15 2007

Mr. Leon Wortham,
President and CEO
Wortham Laboratories, Inc.
6340 Bonny Oaks Drive
Chattanooga, TX 37416

Re: k060968
Trade/Device Name: Wortham Laboratories Stasis 1 Coagulation Control (Normal)
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for in vitro coagulation studies.
Regulatory Class: Class II
Product Code: GIZ, GGC, GGN, GJS, GFO, GIL, KQJ
Dated: April 05, 2007
Received: April 09, 2007

Dear Mr. Wortham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Stasis 1 Coagulation Control (Normal)

Indications For Use:

Wortham Laboratories Stasis 1 Coagulation Control (Normal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Fibrinogen assays. It will yield PT, APTT, and Fibrinogen values in the normal range.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Stasis 2 Coagulation Control (Abnormal)

Indications For Use:

Wortham Laboratories Stasis 2 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the moderate abnormal range.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Stasis 3 Coagulation Control (Abnormal)

Indications For Use:

Wortham Laboratories Stasis 3 Coagulation Control (Abnormal) is intended for use as a quality control to monitor the performance of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT). It will yield PT, and APTT values in the strongly abnormal range.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Serathan-B PT Reagent

Indications For Use:

Wortham Laboratories Serathan-B PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-B is a moderately sensitive thromboplastin reagent.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Serathan-A PT Reagent

Indications For Use:

Wortham Laboratories Serathan-A PT reagent is an in-vitro diagnostic reagent intended in a clinical laboratory for the quantitative determination of Prothrombin Time (PT) testing for the detection of coagulation abnormalities in the extrinsic pathway. Serathan-A is a highly sensitive thromboplastin reagent.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Intrin-EA APTT Reagent

Indications For Use:

Wortham Laboratories Intrin-EA APTT is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-EA reagent is sensitive to mild coagulopathies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Intrin-SI APTT Reagent

Indications For Use:

Wortham Laboratories Intrin-SI is an in-vitro diagnostic reagent used in the clinical laboratory for the quantitative determination of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway. Intrin-SI reagent is sensitive to heparin and lupus anticoagulant plasmas.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Fibrinogen Control Plasma Low

Indications For Use:

Wortham Laboratories Fibrinogen Control Low, a quantitative control plasma, is intended for use in the quality control of fibrinogen assays.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Fibrinogen Control Plasma Normal

Indications For Use:

Wortham Laboratories Fibrinogen Control Normal, a quantitative control plasma, is intended for use in the quality control of fibrinogen assays.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(...) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Thrombin Reagent

Indications For Use:

Wortham Laboratories Thrombin Reagent is intended for thrombin to convert fibrinogen in the quantitative determination of fibrinogen in plasma samples.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ision Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

...(K) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Fibrinogen Assay Set

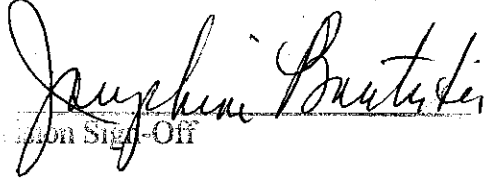
Indications For Use:

Wortham Laboratories Fibrinogen Assay Set, containing a complete set of Normal Fibrinogen Control (200-400 mg/dl), Thrombin Reagent (100 IU/ml), and Fibrinogen Buffer, is intended for use in the quantitative determination of fibrinogen in plasma samples.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



...ion Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Heparin Control Plasma Level 1

Indications For Use:

Wortham Laboratories Heparin Control Level 1, is intended as a quality control of the Activated Partial Thromboplastin Time (APTT) during heparin monitoring.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Heparin Control Plasma Level 2

Indications For Use:

Wortham Laboratories Heparin Control Level 2, is intended as a quality control of the Activated Partial Thromboplastin Time (APTT) during heparin monitoring.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

...ion Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Calcium Chloride Solution 0.02 M

Indications For Use:

Wortham Laboratories Calcium Chloride Solution 0.02 M ($CaCl_2$) is intended for quantitative use with ellagic acid (Intrin-EA) or silicon particulate activators (Intrin-SI) in performing the activated partial thromboplastin time (APTT) on citrated plasma.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce Strauss
(Division Sign-Off)

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060968

Indications for Use

510(k) Number (if known): K060968

Device Name: Wortham Laboratories Fibrinogen Buffer

Indications For Use:

Wortham Laboratories Fibrinogen Buffer is designed as a diluent for fibrinogen studies.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060968